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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR . .	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/736,493	12/15/2003	Kenneth P. Reever	BSC-168DV	3812

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EXAMINER	
BLANCO, JAVIER G	
ART UNIT	**PAPER NUMBER**
3738	

DATE MAILED: 11/14/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/736,493	REEVER, KENNETH P.	
	Examiner	Art Unit	
	Javier G. Blanco	3738	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *30 August 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *7-17* is/are pending in the application.

4a) Of the above claim(s) *8, 13, 16, and 17* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *7,9-12,14 and 15* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *10/14/2004*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Response to Amendment

1. Applicant's cancellation of claims 1-6 in the reply filed on December 15, 2003 is acknowledged.

Election/Restrictions

2. Applicant's election with traverse of **Stent:** Species C (embodied in Figure 8A) in the reply filed on August 30, 2006 is acknowledged. It is noted that the Applicant did not make an election on the "**Stylet**" group of species. The traversal is on the ground(s) that "*it will not be a serious burden on the Examiner to examine all pending claims*".

This is not found persuasive because, as defined in MPEP 808.01(a), for an Election of Species "*it is not necessary to show a separate status in the art or separate classification*". Also, that same section of the MPEP teaches that for a multiplicity of species requiring extensive and/or burdensome search, "*a requirement for an election of species should be made prior to a search*". Further, the art of prostatic stent is a crowded art, therefore creating a serious burden on the Examiner to examine all the species.

Furthermore, the Office Action state: "*should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case*".

The requirement is still deemed proper and is therefore made FINAL.

3. Claims 8, 16, and 17 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected species, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on August 30, 2006. It is noted that dependent claim 13 represent the embodiment shown in Figure 8F (disclosed as "Species E" by the Examiner in the Election of Species Requirement). Therefore, claim 13 is also withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected species.

Specification

4. The disclosure is objected to because of the following informality: please update the "Cross-Reference to Related Applications" section (i.e., now US 6,685,745 B2). Appropriate correction is required.

Claim Objections

5. Claims are objected to because of the following informalities:

a. Regarding claim 7, please **(i)** substitute "a stent" (see line 1) with --a prostatic stent--, and **(ii)** substitute "the external sphincter" (see line 2) with --the external urinary sphincter--. Appropriate correction is required.

b. Regarding each of claims 10, 12, and 15, the limitation "but not limited" (see line 2) is an improper Markush limitation. See M.P.E.P. 2173.05(h).

Claim Rejections - 35 USC § 112

6. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

7. Claims 7, 9-12, 14, and 15 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

a. Regarding claim 7, the limitation "the external sphincter" (see line 2) lacks antecedent basis. Claims 9-12, 14, and 15 depend on claim 7.

Double Patenting

8. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

9. Claims 7, 9-12, 14, and 15 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-7 of U.S. Patent No. 6,685,745 B2. Although the conflicting claims are not identical, they are not patentably distinct from each other because the difference between claims 7, 9-12, 14, and 15 of the application and claims 1-7 of the patent lies in the fact that the patent claims include many more elements and is

thus much more specific. Thus the invention of claims 1-7 of the patent is in effect a "species" of the "generic" invention of claims 7, 9-12, 14, and 15. It has been held that the generic invention is "anticipated" by the "species". See In re Goodman, 29 USPQ2d 2010 (Fed. Cir. 1993). Since claims 7, 9-12, 14, and 15 of the application are anticipated by claims 1-7 of the patent, it is not patentably distinct from claims 1-7.

Claim Rejections - 35 USC § 102

10. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

11. Claims 7 and 11 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Devonec (US 5,766,209 A; cited in Applicant's IDS).

Referring to Figures 1, 2, and 13, Devonec '209 discloses a stent comprising:

(i) A first segment (**first interpretation:** tubular segment 9; **second interpretation:** tubular segment 9 + proximal portion of sleeve 10) including an external surface, and internal surface, a proximal portion, a distal end, a lumen defined by the internal surface and extending within the first segment, and a plurality of openings (**first interpretation:** perforations 9c, as shown in Figure 6; **second interpretation:** perforations 51, as shown in Figure 13; **third interpretation:** perforations on the proximal portion of sleeve 10, as shown in Figures 5b and 5c), the proximal

portion including at least one opening (Figure 1: proximal opening on proximal end) in communication with the lumen;

(ii) A second segment (11) including an external surface, and internal surface, a proximal end, a distal end, a lumen defined by the internal surface and extending within the second segment; and

(iii) A connecting segment (10) disposed between the first and second segments and coupling together the first and second segments.

Devonec also discloses that each of the tubular segments 9 and 11 "can be coated on its outer surface with a therapeutic substance" (see column 6, lines 4-5). Devonec further discloses a method of positioning the claimed structure of the stent within the urinary system (see column 6, lines 24-67; column 7, lines 1-43).

12. Claims 7 and 11 rejected under 35 U.S.C. 102(b) as being clearly anticipated by Tihon (US 5,865,815; cited in Applicant's IDS).

Referring to Figures 1 and 4, Tihon '815 discloses a stent comprising:

(i) A first segment (zone 1 + zone 2) including an external surface, and internal surface, a proximal portion, a distal end, a lumen (26) defined by the internal surface and extending within the first segment, and a plurality of openings (bores 28 on zone 2), the proximal portion including at least one opening (bores 28 on zone 1) in communication with the lumen;

(ii) A second segment (zone 4) including an external surface, and internal surface, a proximal end, a distal end, a lumen defined by the internal surface and extending within the second segment; and

(iii) A connecting segment (zone 3) disposed between the first and second segments and coupling together the first and second segments. The stent is impregnated with a self-eluting drug (see entire document).

13. Claims 1, 9, 11, and 14 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Alt et al. (US 5,788,979; cited in Applicant's IDS).

Referring to Figures 3 and 5, Alt et al. '979 discloses a stent comprising:

(i) A first segment (proximal segment/end of the stent) including an external surface, and internal surface, a proximal portion, a distal end, a lumen (central lumen) defined by the internal surface and extending within the first segment, and a plurality of openings (see Figures 3 and 5), the proximal portion including at least one opening (end of proximal segment/end of the stent) in communication with the lumen;

(ii) A second segment (distal segment/end of the stent) including an external surface, and internal surface, a proximal end, a distal end, a lumen defined by the internal surface and extending within the second segment; and

(iii) A connecting segment (middle segment/portion of the stent) disposed between the first and second segments and coupling together the first and second segments.

The stent comprises a polymerizable hemostatic agent on the external surface, and an anticoagulant of the internal surface (see column 6, lines 8-13; see Examples).

14. Claim 7 is rejected under 35 U.S.C. 102(e) as being clearly anticipated by Devonec (US 6,238,368 B1; cited in Applicant's IDS).

Referring to Figures 1-3, 8, 16, and 17, Devonec '368 discloses a stent (1) comprising:

(i) A first segment (tubular element 3 + medicinal sleeve 7) including an external surface, and internal surface, a proximal portion, a distal end, a lumen (4) defined by the internal surface and extending within the first segment, and a plurality of openings (radial channel 9), the proximal portion including at least one opening (13) in communication with the lumen;

(ii) A second segment (tubular element 14) including an external surface, and internal surface, a proximal end, a distal end, a lumen defined by the internal surface and extending within the second segment; and

(iii) A connecting segment (sleeve 16) disposed between the first and second segments and coupling together the first and second segments. The stent is impregnated with a self-eluting drug (see entire document). Medicinal sleeve 7 contains a drug (see Abstract; see entire document).

Claim Rejections - 35 USC § 103

15. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

16. Claims 9, 10, 12, 14, and 15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Devonec (US 5,766,209 A; cited in Applicant's IDS) in view of Donovan et al. (5,833,651 A; cited in Applicant's IDS).

Devonec discloses the invention as claimed (see 102(b) rejection above). Although Devonec discloses that each of the tubular segments 9 and 11 "can be coated on its outer surface

with a therapeutic substance" (see column 6, lines 4-5), he did not disclose the use of a hemostatic agent on the external surface of the tubular elements and an anticoagulant on the internal surface of the tubular elements. However, Donovan et al. disclose a stent (see column 13, lines 66-67; column 14, lines 1-9) comprising a hemostatic agent (i.e., fibrin) on the external surface of the stent (see column 5, lines 61-67; column 8, lines 13-17) and an anticoagulant (i.e., heparin) on the external surface of the stent (see column 15, lines 15-26) in order to convey a therapeutic action(s) in the area (i.e., urinary tract) to be treated (see entire document). It would have been obvious to one of ordinary skill in the art at the time the invention was made to have combined the teaching of a stent comprising a hemostatic agent on the external surface of the stent and an anticoagulant on the external surface of the stent, as taught by Donovan et al., with the stent of Devonce, in order to convey a therapeutic action(s) in the area to be treated.

With regards to the specific anticoagulants and hemostatic agents, it would have been obvious to one having ordinary skill in the art at the time the invention was made to have used any of the listed anticoagulants and hemostatic agents with the stent of Devonec '209, since it has been held to be within the general skill of a worker in the art to select a know material on the basis of its suitability for the intended use as a matter of obvious design choice. *In re Leshin*, 125 USPQ 416.

17. Claims 10, 12, and 15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Alt et al. (US 5,788,979; cited in Applicant's IDS).

Alt et al. disclose the invention as claimed except for particularly claiming the specific anticoagulants and hemostatic agents claimed in claims 10, 12, and 15. It would have been obvious to one having ordinary skill in the art at the time the invention was made to have used

any of the listed anticoagulants and hemostatic agents with the stent of Alt et al. '979, since it has been held to be within the general skill of a worker in the art to select a know material on the basis of its suitability for the intended use as a matter of obvious design choice. *In re Leshin*, 125 USPQ 416.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Javier G. Blanco whose telephone number is 571-272-4747. The examiner can normally be reached on M-F (9:30 a.m.-7:00 p.m.), first Friday of the bi-week off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott can be reached on (571) 272-4754. The fax phone numbers for the organization where this application or proceeding is assigned is 571-273-8300 for regular communications and After Final communications. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0858.

JGB

November 11, 2006

David H. Willse
Primary Examiner